REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 2-4, 7, 8, 10-12 and 16-27 are pending in the application. Claims 2-4, 7, 8, 10-12 and 16 remain unchanged.

Claims 17-27 are new. Support for new claims 17-27 may be found generally throughout the specification and in the original claims. In particular, support for claims 17-27 may be found in the Examples of the present specification (see Test Example 2, Experiments 1 and 2, and Test Example 3).

Applicants respectfully submit that no new matter has been added.

In the outstanding Official Action, claims 2-4, 7, 8 and 16 were rejected under 35 U.S.C. §102(a) as allegedly being anticipated by KATOH et al. This rejection is traversed.

KATOH discloses a prophylactic and/or therapeutic composition for urinogenital infectious diseases, wherein the composition contains *Lactobacillus salivarius*. KATOH neither discloses nor suggests that the composition can be used to treat gingivitis, periodontitis, periodontal disease, as recited in claims 2-4, 7, and 8.

Nevertheless, the Official Action takes the position that KATOH anticipates the claimed invention. In doing so, the Official Action makes the unsupported allegation that the *Lactobacillus salivarius* strain disclosed by KATO is the same as that claimed. The Official Action contends that "merely because

a characteristic of a known strain is not disclosed in the reference does not make the known strain patentable. The new strain possesses inherent characteristics which might not be displayed in the tests used the reference."

Applicants respectfully submit that the position taken by the Official Action is improper as a matter of law.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined

to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.

Thus, the fact that KATOH may or may not exhibit similar characteristics is insufficient for the Official Action to rely on the KATOH publication as an "anticipatory reference".

Moreover, the present specification does provide evidence that the claimed strains exhibit unique and non-obvious properties. For example, the Examiner's attention is respectfully directed to Test Example 3. Test Example 3 shows that the results of a clinical test that studies the superior effectiveness of the claimed live bacterium preparation and isolated strain. The test results are discussed on page 27 of the specification and shown in Figures 3-9. The test results show that the claimed bacterium preparation and isolated strain are effective in treating halitosis, not harmful to the human intraoral microflora, and helpful in maintaining a normal intraoral pH. The safety of the claimed live bacterium preparation and isolated strain have also been confirmed by clinical testing.

In this regard, Applicants respectfully submit that the position taken by the Official Action is improper as a matter of law. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Applicants further note that while KATOH discloses a probiotic product. However, KATOH does not disclose any *in vivo* data for their product. Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit on the host. The live microorganisms can then survive at a target

site to exhibit desired effects. In order to examine whether cells can function in such a way, *in vitro* tests are insufficient. Indeed, even non-human *in vivo* tests in rodents may be insufficient. This is because the microflora of animals, such as rodents is considerably different from that of humans. In this regard, KATOH is a non-enabling publication.

The tests disclosed by KATOH are all *in vitro* tests performed in culture dishes. This means that the usefulness or effectiveness of the product of KATOH as a probiotic has not been fully established. Whether the product of KATOH can be useful or effective as an anticariogenic or antiperiodontitic probiotic remains unknown.

For example, the strains of KATOH were identified as strongly acid-resistant strains (U.S. Patent Published Application No. 2003157079, [0013], [0014], [0026 to [0028]). It is known that the cariogenic bacteria such as *Streptococcus mutans* and *Streptococcus sorbinus* produce biofilms and favorably proliferate in an anaerobic and acidic condition under the formed biofilms to produce acid as a metabolite and advance dental caries. In this regard, is likely that the strongly acid-resistant bacteria of KATOH would not only survive, but proliferate in an acidic condition produced by cariogenic bacteria to produce lactic acid aggravate, and may even exacerbate tooth decay.

In contrast, the present invention is based on the finding of a specific bacterial cell strain, and confirmation of its usefulness as an anti-cariogenic or anti-periodontitic probiotic via *in vivo* tests. This includes clinical testing in humans.

The live cells of the *Lactobacillus* bacterium of the present invention exhibit superior anticariogenic and antiperiodontitic effects (see Test Example 3, 2, 6, 7). For example, they are not harmful to human intraoral microflora and they can maintain human intraoral pH within a normal range (intraoral pH of patients from 5.4 to 8.5 before intake is converged to the normal range around pH 7.3).

Thus, it has been demonstrated that the preparation containing the strain of the present invention was useful and effective as a probiotic, and not harmful to hosts. In particular, the finding that the strain of the present invention does not lower the intraoral pH, even though it is a lactic acid bacterium, negates the concern that a lactic acid bacterium would exacerbate tooth decay.

Furthermore, the Applicant notes that bacterial strains of the same species generally show different phenotypes at the strain level, because of single nucleotide polymorphism (SNP), difference in expressions of individual genes, and so forth. Therefore, it cannot be assumed that two different strains of the same bacterium would possess the same characteristics.

In view of the above, applicants respectfully request that the rejection be withdrawn.

CLAIMS 17-27

Applicants respectfully submit that KATOH particularly fails to disclose or suggest claims 17-27.

Claim 17 is based on the results of Test Example 1. When the lactic acid bacterium of the present invention is cultured with *Streptococcus mutans,* the

bacterium reduces the amount of insolubles produced by *Streptococcus mutans* by as compared with the amount of insoluble glucan produced by *Streptococcus mutans* cultured alone, i.e., suppresses the insoluble glucan production of *Streptococcus mutans* by 80% (see Table 1 in the present specification). On the other hand, the WB21 strain of KATOH reduced insoluble glucan production by *S. mutans* to about 50% (see Table 13 of KATOH).

The recitation of claims 18-19 and 20-22 correspond to the results of Test Example 2, Experiments 1 and 2, and Test Example 3, respectively.

Claim 21 recites the characteristic of reducing halitosis. Claim 22 recites reducing the number of periodontopathic bacteria. These claims are based on the observation that halitosis is the production of volatile sulfurated compounds such as H_2S, CH_3SH, thiols and sulfides periodontopathic bacteria as described in the present specification (see Test Example 3, Test Results (7)). Halitosis and cell number of periodontopathic bacteria are in a positive correlation.

Claim 23 is based on Test Example 4 (Table 2). In the case of erythritol, for example, bacterial number of *S. mutans* was reduced from 4.0×10^5 (CFU/ml) to 1.0×10^5 (25%) with erythritol alone, and reduced from 4.0×10^5 to 2.0×10^5 (50%) with the lactic acid bacterium of the present invention alone. The reduction ratio expected by simply multiplying these reduction ratios (25% x 50%) is 12.5%. However, the bacterial number was actually reduced from 4.0×10^5 to 1.0×10^4 (2.5%) with erythritol and the lactic acid bacterium of the present invention. Such an effect of the lactic acid bacterium of the present invention and the oral care drug would not have been obvious from KATOH.

In view of the above, Applicant respectfully requests that the KATOH rejection be withdrawn.

Claims 10-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over KATOH et al in view of KLUEPPEL. This rejection is traversed.

KLUEPPEL discloses and oral and dental preparation containing as an active ingredient a C_{2-4} alkoxylated trihydric to hexahydric C_{3-12} aliphatic polyol wherein at least one hydroxyl moiety is esterified with phosphoric acid, or a physiologically compatible water soluble salt thereof (abstract).

However, KLUEPPEL fails to disclose or suggest a strain as recited in any of the claims. In this regard, KLUEPPEL fails to remedy the deficiencies of KATO for reference purposes.

Therefore, the present invention would not have been obvious over KATOH and KLUEPPEL.

Conclusion

In view of the present Amendment and foregoing Remarks, therefore, Applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Respectfully submitted,

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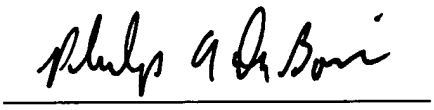
By: 

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